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EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/03/2004.

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/742,096**

Applicant(s)  
**DRUILHE et al.**

Examiner  
**James L. Grun, Ph.D.**

Art Unit  
**1641**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 6 Nov 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-54 is/are pending in the application.
- 4a) Of the above, claim(s) 30-34, 36-38, 40-42, 45-47, and 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35, 39, 43, 44, and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 27-54 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

Applicant's election with traverse of Group I, claims 27-29, 35, 39, 43, 44, and 48, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the Office has provided insufficient reasons, examples, or evidence of different uses or functions of the inventions as grouped. This is not found persuasive because the explanations of different structures, functions, classifications, and fields of search made in the restriction requirement of record are sufficient to provide a *prima facie* showing of a serious burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

The amendment filed 04 February 2002 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the serial number of the prior parent application in the sequence listing, item <150>, should be corrected to --US 08/973,462--.

Applicant is required to cancel the new matter in the response to this Office action.

Applicant is required to provide a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, which includes each of the sequences disclosed in the specification as required by 37 CFR 1.821(c). A substitute copy of the "Sequence

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Listing" in computer readable form must be provided as required by 37 CFR 1.821(e). Applicant must also provide a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). Failure to comply with these requirements will result in  
5 ABANDONMENT of the application under 37 CFR 1.821(g).

This application has been filed with informal drawings which are acceptable for examination purposes only. If applicant intends to retain "SEQ ID NO:" identifiers, such should be consistent with those as listed in the Sequence Listing. Applicant is now required to submit corrected drawings acceptable for publication within the time period set in the Office action. See 37 CFR 1.85(a).  
10 Submission of corrected drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

35 U.S.C. 101 reads as follows:

15           Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 27-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. There is no indication that the product(s) as claimed is/are isolated and no claimed degree of purity for the product(s) which would indicate "the hand of man". Thus, the product(s) as claimed is/are considered a product(s) of nature. A product of nature is non-statutory  
5 subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated  
10 by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 27-29, 35, 39, 43, 44, and 48 are rejected under 35 U.S.C. 112, first paragraph, as  
15 containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is noted by the examiner that applicant's examples are  
20 substantially drawn to the use of those peptides specifically excluded by the instant claims. Absent

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any guidance to those peptides, other than those peptides which have been excluded, which predictably function for any given purpose in the invention, extensive random unpredictable experimentation would be required to determine useable peptide molecules for any given purpose. Such experimentation is undue experimentation. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Moreover, the specification lacks adequate description and enablement of the invention as instantly claimed because the sequence designated in claim 27 as "(729S)" (SEQ ID NO: 11) is not found by the examiner in the sequence of Fig. 2 (i.e. SEQ ID NO: 3). One would be unable to practice the invention as instantly claimed because one would be unable to exclude that which does not exist. Applicant is requested to direct the Examiner's attention to specific residues in the sequences of Fig. 2 which support the invention as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 35, 39, 43, 44, and 48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 27 and claims dependent thereupon, the metes and bounds of the polypeptide molecule for which applicant desires protection is not clear because it is not clear if only the polypeptides consisting of the recited sequences are to be excluded, as may appear applicant's intent given the sequence similarities of the sequences to be excluded, or if any part thereof having at least 10 consecutive residues is to be excluded. It is also unclear if applicant intends a Markush group. If so, proper Markush language should be used. In these claims, "the amino acid sequence" lacks antecedent basis and it is believed that applicant intended SEQ ID NO: 3 of the sequence listing as the sequence because SEQ ID NO: 2 is a nucleic acid sequence and not an amino acid sequence.

In claim 35, multiple elements lack antecedent basis, i.e. "the" diagnosis, reagents, medium, reaction, antigen/antibody complexes, immunological reaction, or case all lack antecedent basis. Moreover, "at least one polypeptide molecules" lacks antecedent basis as claim 27 recites "A polypeptide molecule." This claim is vague and indefinite as to how many or what kind of reagents or reactions or labels are intended and for what the reagents and medium are appropriate, or what relationship any of the components bear to any of the other assay components. Regarding claim 35, the phrase "more especially" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

In claims 39 and 44, "a polypeptide" should be --the polypeptide-- for proper reference to the antecedent component.

In claims 43 and 48, "a polypeptide" should be --the polypeptide-- for proper reference to the antecedent component. The subject matter of these claims appears duplicative of that of claims 39

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and 44, because the polypeptides of the corresponding claims are identical. These claims to a conjugate do not properly limit an independent claim to a method.

In claims 44 and 48, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

5           The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10           (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15           (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 27-29 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Barnes et al. (Exp. Parasitol. 81: 79-89, August 1995).

20           Barnes et al. disclose the "d260" polypeptide (Fig. 2), a polypeptide longer than any of those excluded and contains many sequences, identical to those in instant Fig. 2, being at least 10-mer polypeptides shorter or longer than those excluded.

Applicant cannot rely upon the foreign priority claim to overcome this rejection because the requirements of 35 U.S.C. § 119 have not been met in either the parent application (see Form



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PCT/DO/EO/903 therein) or in the instant application. Moreover, a translation of said papers has not been made of record in the instant application.

Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. See the evidence below.

5           Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Guerin-Marchand et al. (WO 92/13884) in light of the translation provided in Guerin-Marchand et al. (U.S. Pat. No. 6,270,771).

Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Guerin-Marchand et al. (U.S. Pat. No. 6,319,502).

10           The publications of Guerin-Marchand et al., having a different inventive entity than the instant application, contain essentially identical disclosure. The references disclose the "729S" polypeptide (Fig. 3; and SEQ ID NO: 24 in '771 and '502). The references teach that all or part of the polypeptide are encompassed, all or part meaning at least 4-5 amino acid residues up to the full sequence described (see e.g., in '502 and '771, col. 6, lines 64-67). The 729S sequence of the  
15           references anticipates the invention as instantly claimed in being a polypeptide longer than any of those excluded and containing many sequences, identical to those in instant Fig. 2, being at least 10-mer polypeptides shorter or longer than those excluded. The polypeptide is for use in methods and kits for the diagnosis of malaria by the detection of antibodies in sera samples binding to microtiter plate-adsorbed polypeptide using labelled reagents (see e.g., in '502 and '771, cols. 13-14).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (703) 872-9306.

10 Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
James L. Grun, Ph.D.  
February 25, 2004

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641